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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/504,393	02/15/2000	Heinrich Bachmann	20347/111656	7833

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	19

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/504,393	Applicant(s) BACHMANN ET AL.	
	Examiner Yong Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 10-36* is/are pending in the application.

4a) Of the above claim(s) *1-5,16-18 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,10-15,19-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-6 and 10-36 are pending.

Election/Restrictions

Claims 1-5, 16-18 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Response to Arguments

In view of the appeal brief filed on October 15, 2002, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

The utility rejections under 35 USC § 101 and 35 USC § 112, 1st paragraph from the Final Office Action are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 10-15, 19-32 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to DNA encoding a polypeptide of SEQ ID NO: 1. The specification only teaches how to determine a polypeptide as being a β,β-carotene 15,15'-dioxygenase (Example 1) and the specification only teaches how to use a β,β-carotene 15,15'-dioxygenase.

However, Applicants have admitted to the misidentification of the function of the enzyme represented by SEQ ID NO:1. Applicants have admitted that post filing studies revealed SEQ ID NO:1 to be a β,β-carotene 15,15'-monooxygenase rather than a β,β-carotene 15,15'-dioxygenase (Response filed August 3, 2001, page 4). The specification does not teach that SEQ ID NO:1 is a β,β-carotene 15,15'-monooxygenase nor how to use SEQ ID NO:1 as a β,β-carotene 15,15'-monooxygenase. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Art teaches that monooxygenases and dioxygenases have different function. Monooxygenases incorporate one hydroxyl group into their substrates whereas dioxygenases incorporates two atoms of oxygen into their substrates (Harayama, page 566 and abstract).

Applicants argue that the structure of the enzyme remains the same, ~~just its name~~. However, the name "dioxygenase" and "monooxygenase" impart different function and use of the enzyme. The specification teaches how to use SEQ ID NO:1 as a dioxygenase to transform carotene into retinal, as indicated by its name throughout the specification. However, at the time of filing, the specification does not teach now to use SEQ ID NO:1 as a monooxygenase in transforming carotene into retinal.

Even though both enzymes transform carotene to retinal, each reaction is different, leading to different intermediates and use of different cofactors, transition metals, flavin and/or pteridine (Harayama et al., page 566). For example, monooxygenases utilize FAD and the second atom of oxygen is reduced to water either by the substrate themselves or by a co-substrate reductant (Pfam database of protein

families Web Printout). Another example is that a dioxygenase mechanism of a carotene cleavage results in a dioxetane intermediate whereas a monooxygenase mechanism of a carotene cleavage results in an epoxide intermediate (Leuenberger et al., page 2615, 2nd-3rd paragraph). Therefore, the two enzymes are not exchangeable without altering the reaction mixture and the specification specifically only teaches the use of a dioxygenase.

Also, Applicants have admitted ~~to~~ that the consequence of the error in misnaming the enzyme is that the reaction mechanism suggested by the name is different (Appeal Brief, page 14, 3rd paragraph). Since the reaction mechanism is different, using a monooxygenase instead of a dioxygenase necessitates different reactants. Therefore, using a monooxygenase in a reaction scheme set up for a dioxygenase will not yield the same product because the two enzymes utilize different cofactors, transition metals, flavin and/or pteridine.

Even though monooxygenases are well known in the art, it would not have been obvious to one skilled in the art to practice the instant invention as a monooxygenase. At the time of filing, one of skill in the art would not have known to use SEQ ID NO:1 as a monooxygenase because the specification very clearly states that SEQ ID NO:1 is a β,β-carotene 15,15'-dioxygenase.

Therefore, one of ordinary skill would require guidance in order to use SEQ ID NO:1 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claims 6, 10-15, 19-32 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to DNA encoding a polypeptide of SEQ ID NO: 1. Applicants have admitted to the misidentification of the function of the enzyme represented by SEQ ID NO:1. Applicants have admitted that post filing studies revealed SEQ ID NO:1 to be a β,β-carotene 15,15'-monooxygenase rather than a β,β-carotene 15,15'-dioxygenase (Response filed August 3, 2001, page 4). The specification does not describe SEQ ID NO:1 as a β,β-carotene 15,15'-monooxygenase, but rather as a β,β-carotene 15,15'-dioxygenase.

Even though the structure of the enzyme remains the same, the name of an enzyme connotes a specific function to the enzyme and its use. Monooxygenases incorporate one hydroxyl group into their substrates whereas dioxygenases incorporates two atoms of dioxygen into their substrates, as discussed above. Even though both enzymes transform carotene to retinal, each reaction is different, leading to different intermediates and use of different co-factors, as described above.

The specification only describes how to use the claimed invention as a dioxygenase and not as a monooxygenase. Also, the specification only describes assaying a polypeptide for β,β-carotene 15,15'-dioxygenase activity and not for β,β-carotene 15,15'-monooxygenase activity. Therefore, at the time of filing, a skilled

artisan would not recognize from the specification that applicants were in possession of a polypeptide with β,β-carotene 15,15'-monooxygenase activity.

Therefore, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 6, 10-15, 19-32 and 34-36.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

December 30, 2002

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